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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,195	09/14/2001	Martin John Glenton Hughes	GJE-71	7256

23557 7590 12/29/2003

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/868,195	Applicant(s) HUGHES ET AL	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

The preliminary amendment has been entered into the record. Claims 1-12 have been canceled and new claims 13-31 have been added.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 13, 14 and 19-20 (in part), drawn to MS4 peptides, homologues and fragments, *[The first recited technical feature]*.

Group 2, claim(s) 15-18 and 19-20 (in part), drawn to nucleic acids encoding MS4 peptides, homologues and functional fragments.

Group 3, claim(s) 21 and 22, drawn to methods of using MS4 peptides for screening potential drugs.

Group 4, claim(s) 23 and 24, drawn to methods of using MS4 peptides for determining virulence.

Group 5, claim(s) 25-29 (in part), drawn to therapy using MS4 peptides.

Group 6, claim(s) 25-29 (in part), drawn to therapy using MS4 encoding nucleic acids.

Group 7, claim(s) 30-31, drawn to antibodies raised against MS4.

Group 8, claim(s) 13, 14 and 19-20 (in part), drawn to MS10 peptides, homologues and fragments.

Group 10, claim(s) 15-18 and 19-20 (in part), drawn to nucleic acids encoding MS10 peptides, homologues and functional fragments.

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Group 11, claim(s) 21 and 22, drawn to methods of using MS10 peptides for screening potential drugs .

Group 12, claim(s) 23 and 24, drawn to methods of using MS10 peptides for determining virulence.

Group 13, claim(s) 25-29 (in part), drawn to therapy using MS10 peptides.

Group 14, claim(s) 25-29 (in part), drawn to therapy using MS10 encoding nucleic acids.

Group 15, claim(s) 30-31, drawn to antibodies raised against MS10.

Group 16, claim(s) 13, 14 and 19-20 (in part), drawn to MS11 peptides, homologues and fragments .

Group 17, claim(s) 15-18 and 19-20 (in part), drawn to nucleic acids encoding MS11 peptides, homologues and functional fragments.

Group 18, claim(s) 21 and 22, drawn to methods of using MS11 peptides for screening potential drugs .

Group 19, claim(s) 23 and 24, drawn to methods of using MS11 peptides for determining virulence.

Group 20, claim(s) 25-29 (in part), drawn to therapy using MS11 peptides.

Group 21, claim(s) 25-29 (in part), drawn to therapy using MS11 encoding nucleic acids.

Group 22, claim(s) 30-31, drawn to antibodies raised against MS11.

Group 23, claim(s) 13, 14 and 19-20 (in part), drawn to MS14 peptides, homologues and fragments .

Group 24, claim(s) 15-18 and 19-20 (in part), drawn to nucleic acids encoding MS14 peptides, homologues and functional fragments.

Group 25, claim(s) 21 and 22, drawn to methods of using MS14 peptides for screening potential drugs .

Group 26, claim(s) 23 and 24, drawn to methods of using MS14 peptides for determining virulence.

Group 27, claim(s) 25-29 (in part), drawn to therapy using MS14 peptides.

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Group 28, claim(s) 25-29 (in part), drawn to therapy using MS14 encoding nucleic acids.

Group 29, claim(s) 30-31, drawn to antibodies raised against MS14.

Group 30, claim(s) 13, 14 and 19-20 (in part), drawn to MS16 peptides, homologues and fragments .

Group 31, claim(s) 15-18 and 19-20 (in part), drawn to nucleic acids encoding MS16 peptides, homologues and functional fragments.

Group 32, claim(s) 21 and 22, drawn to methods of using MS16 peptides for screening potential drugs .

Group 33, claim(s) 23 and 24, drawn to methods of using MS16 peptides for determining virulence.

Group 34, claim(s) 25-29 (in part), drawn to therapy using MS16 peptides.

Group 35, claim(s) 25-29 (in part), drawn to therapy using MS16 encoding nucleic acids.

Group 36, claim(s) 30-31, drawn to antibodies raised against MS16.

The inventions listed as Groups 1-36 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The first recited technical feature of the first claim (claim 13) is an MS4 peptide or a homolog or functional fragment. The specification describes the MS4 peptide as encoding an ornithine carbamoyltransferase (page This technical feature is not special within the meaning of PCT Rule 13.2 because it does not define a contribution that the invention makes over the prior art. The claim is anticipated by Falmagne et al (Journal of Bacteriology, 161(2):714-719, 1985) which teaches isolation of several ornithine carbamoyltransferases (see paragraph bridging pages 714-715) from bacteria including *Streptococcus faecalis* which anticipates the claims by means of the recitation of "homologues" and "functional fragments" or Tricot et al (Journal of General Microbiology, 135:2453-2464, 1989) which anticipates the claims by means of the recitation of "homologues" and "functional fragments". Since all proteins are

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de facto encoded by nucleic acids this limitation is also met. Inasmuch as, the peptide of claim 13 is anticipated, the nucleic acids and multiple recited methods also lack unity of invention because the technical feature is does not define a contribution over the prior art. Therefore, Groups 1-7 do not share a technical feature that is "special" and as such, unity of invention is not present. As to Groups 8-36, each of these groups are purported to encode different enzymes (phosphoglycerate kinase; glucose-6-phosphate isomerase; purine nucleoside phosphatase; and nonphosphorylating, NADP-dependent glyceraldehyde-3-phosphate dehydrogenase) and therefore fail to share the same technical feature of Group 1, the ornithine carbamoyltransferase.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 703-305-7555. The examiner can normally be reached on M-F 6:30pm-3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Patricia A. Duffy
Patricia A. Duffy
Primary Examiner
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